By the present Amendment, claims 1, 4, 8, 11-16, 19-25, 28, 32, 34, 37, 41, 43, 46, 50 and 52-57 have been amended for various matters of form in accordance with customary U.S. patent practice and/or to more clearly define the invention. It is believed that these changes do not involve any introduction of new matter. Additionally, claims 58-61 have been added. Support for claim 58 may be found in original claim 1 and in the specification at page 6, lines 29-32. Support for claim 59 may be found in original claims 1 and 2 and in the specification at page 8, lines 8-13, and support for claims 60 and 61 may be found in the specification at page 7, lines 2-15. Since these changes do not involve any introduction of new matter, entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner noted Applicants' use of the trademarks/tradenames WPI 97, Whey Peptide, WPC 80 and ION EXCHANGE in the specification. At page 5, these products are described as a source of amino acids and are indicated throughout the specification as tradename products. These products are well know commercially as whey protein and/or whey protein derivatives. It is therefore believed that the specification properly uses the indicated tradenames.

Claims 1, 4, 6-11, 13, 25 and 34 were provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 6-8, 11-15, 17 and 20 of copending application Serial No. 09/420,439. A Notice of Express Abandonment for the copending application Serial No. 09/420,439 is filed on even date as this Amendment. A copy of the Notice as filed is attached. It is therefore submitted that this provisional rejection has been overcome. Reconsideration is respectfully requested.

Claims 1-57 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. As will be set forth in detail below, it is believed that the claims are definite in accordance with

the requirements of 35 U.S.C. §112, second paragraph, whereby this rejection has been overcome. Reconsideration is respectfully requested.

More particularly, the Examiner objected to the use of the terms "substance" and "source" in the claims as being indefinite. While the claims have been amended to delete the term "source", Applicants submit that the term "substance" is definite to one of ordinary skill in the art in view of Applicants' specification. In this regard, the Examiner's attention is directed to the specification at page 5, line 17 - page 6, line 4 and page 6, lines 9-17, wherein suitable substances are described and disclosed. Moreover, the Examiner has not indicated why one of ordinary skill in the art would find "substance" to be indefinite. Finally, in the event that the Examiner maintains the position that the term "substance" is indefinite, Applicants reserve the authority to amend claims 1-57 to replace the term "substance" with the term "component" as employed in claims 58-61.

The Examiner also objected to the phrase "substance which can enhance and/or mimic insulin activity". Claims 4, 28, 37 and 46 have been amended to replace the phrase objected to by the Examiner with the phrase "substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity." Applicants submit that these claims are definite.

The Examiner objected to the use of the term "comprises" in claims 20 and 53. Claims 20-23 and 53-56 have been amended to recite the weight ranges in accordance with customary U.S. patent format.

In claims 25, 28, 32, 34, 37, 41, 43, 46, 50 and 52, the Examiner objected to the term "administering" on the basis that the accepted meaning of the phrase is transitive, with the subject in need of the remedy, not the tool for effecting the remedy, being the object of the

"administering." These claims have been amended to more clearly recite a method which comprises administering to an athlete or individual the food supplement.

Finally, in claims 13, 15 and 16, the Examiner objected to the use of trademarks/ tradenames. These claims have been amended to omit the use of trademarks or tradenames.

It is therefore submitted that the claims are definite in accordance with the requirements of 35 U.S.C. §112, second paragraph. Reconsideration is respectfully requested.

Claims 1, 4, 6-11, 13, 25 and 34 were rejected under 35 U.S.C. §102(f) because the Applicants did not invent the claimed subject matter, the Examiner asserting that the cited claims of the instant application are also seen to be invented by the inventor of copending U.S. Patent Application Serial No. 09/420,439 (the '439 application). The Examiner also indicated that the issue of priority under 35 U.S.C. §102(g) and possibly 35 U.S.C. §102(f) of the single invention of claims 1, 4, 6-11, 13, 25 and 34 of the present application and claims 1, 6-8, 11-15, 17 and 20 of the '439 application must be resolved. Claims 1, 4, 6-11, 13, 25 and 34 were provisionally rejected under 35 U.S.C. §102(e) as being anticipated by the copending '439 application. Finally, claims 2, 3, 5, 12, 19-24, 26, 27, 34-36, 38, 39, 44 and 45 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 3, 5, 13, 14-16, 17 and 20 of the copending '439 application.

For the record, the Applicants of the present application note that the inventor of the '439 application is a coinventor of the present application. However, as noted above, the '439 application is expressly abandoned by the filing of the Notice of Express Abandonment. It is therefore submitted that all rejections under 35 U.S.C. §§ 102, 103 and the judicially created doctrine of obviousness-type double patenting based on the '439 application are moot. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

Finally, claims 1-57 were rejected under 35 U.S.C. §103(a) as being unpatentable over each of the Schneider et al U.S. Patent No. 5,902,829 and the Ham et al U.S. Patent No. 5,324,656. The Examiner asserted that Schneider et al disclose compositional components L-arginine, a carbohydrate source, whey and folic acid while Ham et al disclose components of cell growth enhancing formulations comprising L-arginine, myo-inositol, L-glutamine, L-phenylalanine and folinic acid. The Examiner asserted it would have been obvious to include in a single formulation a substance capable of increased nitric oxide production in a body and a source of amino acid because Schneider et al and Ham et al are in the same field of endeavor, the art of nutritional supplementation for human cells.

However, as will be set forth in detail below, Applicants submit that the food supplements and methods defined by claims 1-57 are nonobvious over and patentably distinguishable from the teachings of Schneider et al and Ham et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 1, the invention is directed to a food supplement comprising a substance which increases nitric oxide production in the body, and amino acids. According to claim 4, the invention is directed to a food supplement which comprises a substance which provides at least one function selected from the group consisting of enhancing insulin activity and mimicking insulin activity, and amino acids. According to claim 8, the invention is directed to a food supplement which increases nitrogen retention in the body comprising a substance which increases nitrogen retention, and amino acids. According to claim 11, the invention is directed to a food supplement comprising a glycosidal saponin, glucomannan, D-chiro-inositol, myo-inositol, and amino acids. According to claim 14, the invention is directed to a food supplement comprising a substance which increases nitric oxide production in the body, and whey protein or a whey protein derivative. According to claim 19, the invention is directed

to a food supplement comprising 1mg-3000mg glycosidal saponins; 1mg-2000mg myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and amino acids.

According to claims 25-33 and 43-57, the invention is directed to methods for increasing an athlete's lean muscle mass and strength. Claims 34-42 are directed to methods for increasing muscle mass and/or strength of an individual. These methods all comprise administering to the athlete or the individual a food supplement.

In contrast to the food supplements, the methods for increasing an athlete's lean muscle mass and strength, and the methods for increasing muscle mass and/or strength of an individual, according to the present invention, Schneider et al disclose methods of modulating microcirculation. More specifically, Schneider et al disclose methods for the amelioration of micro-circulatory hypo-perfusion and/or for the treatment of prophylaxis of hypoperfusion-reperfusion injury in patients which have undergone elective surgery by preoperative administering to the patients a medicament or nutritional formulation containing L-arginine, or a precursor or salt thereof, or a nitric oxide donor, a substrate of the nitric oxide synthetase, and/or a precursor of such a substrate. The medicament or nutritional formulation of Schneider et al is for preventing endothelial damage occurring in reperfusion injury.

Applicants find no teaching or suggestion by Schneider et al relating to methods for increasing an athlete's lean muscle mass and strength as recited in claims 25-33 and 43-57, relating to methods for increasing muscle mass and/or strength of an individual as recited in claims 34-42, or relating to food supplements therefor as defined in the present claims. Moreover, despite the Examiner's assertion that Schneider et al and the present invention are in the same field of endeavor, i.e., the art of nutritional supplementation for human cells, Applicants submit that one of ordinary skill in the art will recognize a significant difference between the field of endeavor of Schneider et al and the art to which the present invention pertains. That is,

one of ordinary skill in the art will easily recognize that the prevention of endothelial cell damage to the cardiovascular system during elective surgery is significantly different from increasing an athlete's lean muscle mass and strength or increasing muscle mass and/or strength of an individual. Smooth muscle cells which are the target of the present methods and food supplements and skeletal muscle cells which are the target of the Schneider et al methods and medicaments are not in the same location within the body and do not have the same function or histology. Thus, Schneider et al do not render obvious either the supplements or methods according to the present invention.

The Examiner's attention is also directed to the specific food supplement compositions of claims 3, 5-7, 10-12, 18-24 and 58-61. The Examiner's attention is also directed to the specific food supplements employed in the methods of claims 27, 29-31, 36, 38-40, 45, 47-49 and 52-57. Applicants find no teaching or suggestion of these supplements by Schneider et al.

References relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of Schneider et al to teach or suggest food supplements and methods as defined by the present claims, Schneider et al fail to provide an enabling disclosure of the presently claimed invention and do not place the claimed invention in the possession of the public. Thus, Schneider et al do not support a rejection under 35 U.S.C. §103.

Ham et al disclose media for normal human muscle satellite cells (HMSC), and particularly an improved basal nutrient medium for the clonal growth of HMSC and serum-free supplements for the clonal growth of such cells. Ham et al disclose that the combination of the basal nutrient medium and the serum-free supplement results in a serum-free medium for growth of such cells which can be transplanted to muscles of patients afflicted with muscle degenerative

diseases such as muscular dystrophy. The HMSC are grown in tissue culture, *in vitro*, not *in vivo*.

However, Applicants find no teaching or suggestion by Ham et al relating to food supplements. Similarly, Applicants find no teaching or suggestion by Ham et al relating to methods for increasing an athlete's lean muscle mass and strength or methods for increasing muscle mass and/or strength of an individual, particularly by administering a food supplement. Again, despite the Examiner's assertion that Ham et al and the present invention are directed to the same field of endeavor, one skilled in the art will readily appreciate that the *in vitro* growth of human muscle satellite cells in tissue culture is significantly distinguishable from food supplements and methods for increasing an athlete's lean muscle mass and strength and methods for increasing muscle mass and/or strength of an individual by administering a food supplement. One skilled in the art will similarly recognize that compositions and concentrations for the macroenvironment of the digestive tract are significantly distinguishable from those required in the microenvironment of *in vitro* cell culture.

The Examiner's attention is also directed to the specific food supplement compositions of claims 3, 5-7, 10-12, 18-24 and 58-61. The Examiner's attention is also directed to the specific food supplements employed in the methods of claims 27, 29-31, 36, 38-40, 45, 47-49 and 52-57. Applicants find no teaching or suggestion of these supplements by Ham et al.

In view of the failure of Ham et al to teach or suggest food supplements, methods for increasing an athlete's lean muscle mass and strength or methods for increasing muscle mass and/or strength of an individual, Ham et al fail to provide an enabling disclosure of the presently claimed invention and fail to place the claimed invention in the possession of the public. Thus, Ham et al do not support a rejection under 35 U.S.C. §103, *In re Payne*, *supra*.

It is therefore submitted that the food supplements and methods defined by claims 1-57 are nonobvious over and patentably distinguishable from Schneider et al and Ham et al, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejections under 35 U.S.C. §§ 101, 102, 103 and 112, second paragraph, and the judicially created doctrine of obviousness-type double patenting, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By _____

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